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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,625	10/23/2003	Michel Therin	114138	5931

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P.O. BOX 19928
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,625

Applicant(s)

THERIN ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 11 December 2006.

Corrections made to the specification and claims are accepted.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Ory et al. (Patent No. 6,451,032 B1)

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ory et al. disclose a process for preparing a composite prosthesis (Figure 1, element 1) comprising the steps of preparing a solution of a hydrophilic absorbable material (collagen and a hydrophilic additive; column 4, lines 18-25), inherently in the

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fluid or liquid state since Ory et al. disclose the material is spread over the support (column 6, line 42), and then is cooled to allow for solidification (gelled by cooling; column 6, lines 54-55). Ory et al. also disclose a porous textile support (column 3, lines 55-56) comprising an arrangement of threads (yarn; column 3, lines 57-58) each composed of at least one filament of nonabsorbable polymer material (polyester; column 5, lines 66-67). Furthermore, the porous textile support (not labeled) is impregnated with the solution since the pores (or interstices that make up the "microporous" texture) of the textile support inherently soak up the solution as it is applied (column 6, line 45). Ory et al. further discloses drying the impregnated part of the textile support (column 6, lines 62-63). Since Ory et al. disclose a reinforcement prosthesis (column 2, lines 28-31), a reinforcement prosthesis is obtainable by the process as described above.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1, 3, 6-10, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Brown et al. (Publication No. US 2003/0023316 A1). Browning discloses a prosthesis (Figure 8a, not labeled) comprising a porous textile support (20) that includes an arrangement of threads (Figure 7a, element 22), each composed of at least one filament of nonabsorbable polymer material (polyester; page 36, line 1;). Browning discloses one thread (22) comprises several filaments (page 35, lines 17-19) of nonabsorbable polymer material (polyester; page 36, line 1), and the blown-up portion of Figure 7 shows the microporous texture additionally comprises interstices (pores 28) between filaments of the same thread (22). Figure 7a shows the textile support (20) constitutes a two-dimensional knitted structure (20), since it is a generally flat mesh/net, defining a microporous texture (the blown up portion of Figure 7a shows interstices between the threads at the sites of contact with one another, thus belonging to the meshes of the knitted structure 20). Figure 7a shows empty spaces (a) defined between threads (22) away from their sites of contact, thus makeup the intermesh spaces of the knitted structure (20).

Browning further discloses a hydrophilic absorbable material (starch or cellulose based hydrogel; page 13, lines 6-10) coats the textile support (page 38, lines 1-2) forming a film enveloping and penetrating into the arrangement of threads and occluding the microporous texture (the strands are entirely embedded; page 38, lines 8-10). Figure 8b shows an embodiment where one face remains uncovered (bottom 36; page 38, lines 27-30). Browning discloses the protected zone (the area covered by the

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absorbable coating 32) has a surface completely covering the textile support (outer surface of the mesh is covered entirely by the absorbable coating; page 38, lines 10-11). Browning discloses the absorbable coating (32) is chosen from the group formed by collagens, polysaccharides, and their mixtures (starch or cellulose based hydrogel; page 13, lines 6-10). Browning discloses the tissue structure is an extraperitoneal tissue since the prosthesis is used to repair hernias, including bladder protrusion (page 6, lines 13-15 and page 1, lines 9-22).

Browning further discloses the textile support (Figure 8a, element 20) defines a macroporous texture (Figure 7a), comprising volumes whose surface is defined by the empty spaces (a) between threads (22) away from their sites of contact, and whose height (not shown) is defined by the thickness of the textile support (20). Browning discloses that the absorbable coating may be applied to one side of the support (top or bottom; page 38, lines 27-32). Therefore, it is obvious the film occludes the macroporosity (holes between non-contacting threads) of the textile support over at least part of the surface (or "zone"). Browning further discloses that the absorbable coating (32) may be applied to both sides of the support (top and bottom) so that the support is encased and has no holes or gaps on either side (page 38, lines 13-17). Therefore, it is obvious the coating occludes the macroporosity (holes between non-contacting threads) of the support (20) over the whole surface (or "zone").

Browning also discloses that the absorbable coating makes the support (20) more substantial and less flexible, thus "preserves the macroporous texture of the textile support" (20) on the surface (or "zone; i.e., the coating keeps the texture from being

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damaged through movement). Browning does not disclose the absorbable material is noncontinuous. Brown et al. disclose a prosthesis (Figure 1, element 10) comprising the shape of a rectangle (strip with parallel edges). Brown et al. disclose the film of absorbable material (small intestine submucosa; 12) is noncontinuous, since it does not cover the entire support (outer edges 30 of the support are devoid of absorbable material), wherein the protected zone (from the first end 20, including sides 24, through the second end 22) represents a central band of the part, since it is a strip through the center of the part. This configuration allows a portion of the prosthesis to act as a scaffold for tissue ingrowth, but at the same time gains additional mechanical strength (paragraph 48). Therefore, to construct the prosthesis of Browning wherein the absorbable material is noncontinuous as taught by Brown et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a prosthesis that is strong, yet promotes tissue ingrowth.

Browning in view of Brown et al. does not disclose the parallel edges of the strip are curved in an arch. Browning discloses the prosthesis may have any shape or size and may be cut to the appropriate dimensions as required by the user (page 37, lines 7-9). Applicant has not disclosed that a strip with curved edges provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with straight edges because the function of the prosthesis is to act as a reinforcement for tissue structures and this function is not affected by its shape. Therefore, it would have

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been obvious to modify the prosthesis of Browning in view of Brown et al. to obtain the invention as claimed in claims 9 and 10.

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Brown et al. as applied to the claims above, and further in view of Ory et al.

Browning in view of Brown et al. discloses a prosthesis as claimed above, however, does not disclose the film has a thickness of less than or equal to 500 microns. Ory et al. disclose a prosthesis (Figure 1, element 1) having a hydrophilic absorbable film with a thickness between approximately 30 microns and 100 microns. This configuration helps the prosthesis to prevent postsurgical adhesions in the treatment of eventrations and hernias (column 2, lines 35-48). Therefore, to construct the prosthesis of Browning in view of Brown et al., wherein the film has a thickness of less than or equal to 500 microns as taught by Ory et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to help prevent postsurgical adhesions.

Browning in view of Brown et al. and further in view of Ory et al. do not disclose the film has a thickness of 10 to 100 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a prosthesis where the film has a thickness of 10 to 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

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7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Brown et al. as applied to the claims above, and further in view of Landgrebe et al. (EP 0774240 A1).

Browning in view of Brown et al. discloses a prosthesis as described above, wherein the center portion is the protected zone and the side portions are the unprotected portions, however, does not disclose the prosthesis has nonparallel edges and a bulged central region. Landgrebe et al. disclose a strip (Figure 1, not labeled) having nonparallel edges (top edge 2 and bottom edge not labeled). Figure 1 shows the device is bulged in the central region (1) and narrower at the ends (5, 6, 7, and 8). This configuration allows the device to support a wide surface area of an organ (bladder; column 1, lines 45-47), thus contributing to a reliable treatment of incontinence in cases of extreme weakness of the pelvic floor with prolapsing anatomical displacement of the organs of the lesser pelvis (column 1, lines 33-39). Therefore, to construct the strip of Browning et al. in view of Brown et al. having nonparallel edges and a bulge as taught by Landgrebe et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to support prolapsed structures on a large surface area.

8. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ory et al.

Ory et al. do not disclose the impregnation step is done by immersing the surface of the textile support in the solution nor discloses the impregnation step is done by spraying the solution on to the surface of the textile support. Ory et al. disclose the

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coating is spread uniformly over the textile support (column 6, line 45), thus impregnating with the solution, since the pores (or interstices that make up the "microporous" texture) of the textile support soak up the solution as it is applied. It is well known in the art to use the methods claimed above. Furthermore, applicant has not disclosed that the methods of immersing or spraying the textile support with the solution provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well if immersed or sprayed because the function of the process is to impregnate the textile support and this function is not affected by method since the textile support is porous. Therefore, it would have been obvious to modify the impregnation step of Ory et al. to obtain the invention as claimed in claims 20 and 21.

Furthermore, Ory et al. do not disclose the viscosity of the solution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a solution having a viscosity of less than or equal to 1000 centipoises, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3, 6, 8-14, and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/690532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are more specific and add features. The structural limitations set forth in claims 1-3, 6, 8-14, and 16-18 of the instant application are also claimed in the copending application, e.g., a porous textile support, an arrangement of threads, at least one filament composed of nonabsorbable polymer material, a hydrophilic absorbable material covering the textile support.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 4-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/690532 in view of Ory et al. The difference between claims 4-5 of the instant application and claim 1 of the copending application is the thickness of the film. Ory et al. teaches the thickness of the film is between approximately 30 microns and 100

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microns. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the thickness of the film as taught by Ory et al. in order to help prevent postsurgical adhesions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/690532 in view of Browning. The difference between claim 7 of the instant application and claim 1 of the copending application is that the protected zone has a surface completely covering that of the textile support. Browning teaches the absorbable material coats the entire surface of the textile support. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis having a protected zone with a surface that completely covers the textile support as taught by Browning, in order to make the prosthesis less susceptible to bacteria and easier to handle during implantation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed 11 December 2006 have been fully considered but they are not persuasive. Applicant argues primarily that the applied references lack each and every element of Applicant's claims. Regarding amended claim 1, see the rejection above for a detailed description of each element. Regarding claim 19,

Applicant argues that the process of Ory is contrary to the process of claim 19, "whereby at least a portion of the support is capable of retaining its porosity, including any macroporosity." The argument with respect to the Ory reference is moot because the process of claim 19 does not recite this limitation (see claim 19).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
January 27, 2007

[Signature]
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
1/27/07